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| 10/007,331      | 11/09/2001  | James C. Paulson     | 019957-011211US     | 3312             |

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EXAMINER

PROUTY, REBECCA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/007,331

Applicant(s)

PAULSON ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57, 59-70 and 101 is/are pending in the application.
- 4a) Of the above claim(s) 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57, 59-65, 67-70 and 101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/01 6) ☐ Other:

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Claims 1-56, 58, 71-100 and 102-111 have been canceled. Claims 57, 59-70, and 101 are at issue and are present for examination.

Applicant's election of ST3Gal III sialyltransferases as a species in the response filed 10/15/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As ST3Gal III does not sialylate oligosaccharides found in O-linked oligosaccharides (see Weinstein et al. page 13846 and Table II), Claim 66 does not read on the elected species and is hereby withdrawn.

Claim 66 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the response filed 10/15/03.

Claims 68-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 (Claims 69-70 dependent thereon) is indefinite in the recitation of "has an amino acid sequence at least about 40% to a sialyl motif from a sialyltransferase selected from the

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group consisting of ST3Gal I, ST6Gal I, and ST3Gal III" as the specification fails to teach the sequence of the sialyl motif from all ST3Gal I, ST6Gal I, and ST3Gal III enzymes. As the sequence of all possible reference sequences is not given it is impossible to determine if another sequence has 40% identity thereto.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57, 59-65, 67-70, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Bergh et al (US Patent 5,272,066), Maras et al (US Patent 5,834,251), Weinstein et al. (JBC 257: 13845) and Williams et al. (Glycoconjugate J. 12: 255).

Each of Bergh et al. and Maras et al. teach methods of *in vitro* enzymatic modification of glycoproteins, particularly natural and recombinant glycoproteins intended for therapeutic applications. Each of Bergh et al. teach that such modifications improve the circulatory half-life of the glycoproteins as well as providing other benefits as well. (see particularly columns 1-3

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of Maras et al. and column 5 or Bergh et al.). Maras et al. teach that the glycoprotein of interest is preferably an immunoglobulin (see column 16, lines 44-46). These methods comprise incubating a glycoprotein either having or having been modified to have a terminal galactose residue in a Gal $\beta$ 1-4GlcNAc or a Gal $\beta$ 1-3GlcNAc linkage with a sialyltransferase and a sialic acid donor. Bergh et al. teach the use specifically of the bovine colostrum or rat liver Gal $\beta$ 1-4GlcNAc  $\alpha$ 2 $\rightarrow$ 6 sialyltransferase (i.e., ST6Gal I) and rat liver Gal $\beta$ 1-3(4)GlcNAc  $\alpha$ 2 $\rightarrow$ 3 sialyltransferase (i.e., ST3Gal III). Maras et al. teach the use specifically of the rat liver Gal $\beta$ 1-4GlcNAc  $\alpha$ 2 $\rightarrow$ 6 sialyltransferase (i.e., ST6Gal I). Maras et al. further teach that as a result of the described methods, that large-scale stereo-controlled oligosaccharide synthesis will be possible (see column 28, lines 52-67). Neither Bergh et al. nor Maras specifically show a commercial-scale method nor do they discuss the extent of sialylation achieved in their methods.

Weinstein et al. teach the enzymatic properties of the sialyltransferases (i.e., rat liver ST6Gal I and ST3Gal III used in the methods taught by Bergh et al. and Maras et al. Weinstein et al. further teach conditions under which each of these enzymes can fully sialylate all available substrate (see Table 4).

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Williams teach the large scale recombinant expression and kinetic properties of the sialyltransferases (i.e., rat liver ST6Gal I and ST3Gal III used in the methods taught by Bergh et al. and Maras et al.

Therefore it would have been obvious to one of skill in the art to use the recombinant enzymes provided by Williams to scale up the methods taught by Bergh et al. and Maras to a commercial scale for the production of therapeutic glycoproteins. One would have had a reasonable expectation of successful scale-up in view of the explicit statement of Maras et al of such expectation and in view of the availability of large quantities of enzyme from recombinant production as taught by Williams. Furthermore, one of skill in the art would have reasonably expected to be able to achieve virtually complete sialylation of all available substrate galactose residues in view of the teaching of Weinstein et al.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57, 59-65, 67-70, and 101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 57, 59-64, 66-69 and 82 of U.S. Patent No. 6,399,363. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 57, 59-65, 67-70, and 101 are generic to all that is recited in claims 57, 59-64, 66-69 and 82 of U.S. Patent No. 6,399,363. That is, claims 57, 59-64, 66-69 and 82 of U.S. Patent No. 6,399,363 fall entirely within the scope of claims 57, 59-65, 67-70, and 101 herein or, in other words, claims 57, 59-65, 67-70, and 101 are anticipated by claims 57, 59-64, 66-69 and

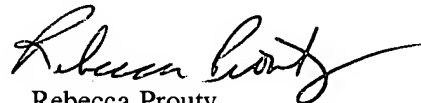
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82 of U.S. Patent No. 6,399,363. Specifically, the claims differ only in that all of the claims of U.S. Patent No. 6,399,363 include limitations that greater than 80% of the available terminal galactose residues are sialylated and that the sialyltransferase is present at a concentration of 50 mU/mg of glycoprotein or less. As such the claims of the previous patent clearly anticipate the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty  
Primary Examiner  
Art Unit 1652